

K072175

510(k) SUMMARY

ADMINISTRATIVE INFORMATION

AUG 21 2007

Manufacturer Name: Orthopedic Sciences, Inc.
3020 Old Ranch Parkway, Suite 325
Los Angeles, CA 90045

Official Contact: James K. Brannon, M.D. President/CEO
Telephone (562) 799-5550 Fax (562) 799-5533

DEVICE NAME

Classification Name: Plate, fixation, bone

Trade/Proprietary Name: Titanium Hip Tool™ Locking Plate

Common Name: Bone plate

PREDICATE DEVICE INFORMATION

The predicate device for this modification is the TS Bone Hip Tool™ Implant, a component of the TS Bone Hip Tool™ Bone Graft Stabilization System, cleared by FDA under K063709.

INTENDED USE

The Titanium Hip Tool™ Locking Plate is intended to stabilize a bone graft within the femoral head and neck to assist healing of an intraosseous fracture.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2007

Orthopedic Sciences, Inc.
% James K. Brannon, M.D.
President/CEO
3020 Old Ranch Parkway, Suite 325
Seal Beach, California 90740

Re: K072175

Trade/Device Name: Titanium Hip Tool™ Locking Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation
appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: August 2, 2007
Received: August 6, 2007

Dear Dr. Brannon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic

product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Mark N. Melkerson", with a small "for" written below it.

Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number: K072175

Device Name: Titanium Hip Tool™ Locking Plate

Indications for Use:

The Titanium Hip Tool™ Locking Plate is intended to stabilize a bone graft within the femoral head and neck to assist healing of an intraosseous fracture.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division Sign-Off

Division of General, Endovascular,
and Neurological Devices

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